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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,457	06/14/2001	Mark D. Cochran	SY01105K1QKQK	7533

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EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/881,457	Cochran et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 2, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above, claim(s) *40-47* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-39* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment B, paper No.12, filed 3/17/2003. Claims 40-47 have been added. Claims 1-47 are pending.

Election/Restriction

Newly submitted claims 40-47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to new and distinct products and methods.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-47 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The amendment filed 3/17/03 is objected to under 35 U.S.C. 132 because it introduces **new matter** into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "corresponds to nucleotide positions 1 to 136,040 of GenBank accession No. AF291866", and "corresponds to nucleotide positions 66 to 11,221 of GenBank

accession No. L22174" is new. No such teaching has been found. Applicants are requested to point to specific page and line where the appropriate recitation maybe located. Applicants have point to page 19, lines 24 to page 23, line 26, and Figure 2 for support. However, the said pages and Figure, do not provide support for "corresponding" sequences. Please clarify.

Claims 1-9, 11-14, 16, 18-21, 23-25, 28-29, 30-33, 34-36, 38-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of "corresponds to nucleotide positions 1 to 136,040 of GenBank accession No. AF291866", and "corresponds to nucleotide positions 66 to 11,221 of GenBank accession No. L22174" is new.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 1-9, 11-14, 16, 18-25, 27-29, 31-33, 35-37, 39 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 9/12/02. Applicants believe the amended claim 1 addresses the Office's concern and the said claim now recites specific regions that are disclosed. Applicant's argument as part of amendment B, Paper

NO. 9, filed 9/12/02 has been considered fully, but they are not persuasive. There are multiple long regions and multiple short regions present within the HVT and Marek's's disease virus respectively. It is not clear which regions are forming the chimeric virus. The regions should be identified with appropriate sequence identification numbers. This affects the dependent claims.

Claim Rejections - 35 USC § 102

Claims 1-3, 5-7, 9, 11, 13, 18, 20, 24, 25, 28-29, 32-33, 36, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Cochran et al (US Patent No. 5,965,138), for reasons of record advanced in the previous Office Action mailed 9/12/02. Applicants argue that ,138 patent does not mention the US2 gene as an insertion site. In addition, applicants argue that the 138, patent contains approximately 22,000 more MDV-derived nucleotide sequence than the present claimed invention. Applicant's argument as part of amendment B, Paper NO. 9, filed 9/12/02 has been considered fully, but they are not persuasive. Applicants assertion that ,138 does not teach US gene as a suitable site is considered to be unsupported, since Figure 3B for instance clearly taught US as suitable site for insertion. In addition, in view of the new matter rejection as stated above the rejection is maintained. Still further, applicants admission on the record of "approximately 22,000 more MDV-derived nucleotide sequence" is interesting since the newly added limitation to claim 1 says "corresponds to nucleotide positions 1 to 136,040" etc.., and since the "corresponds" is not taught and the ratio is not necessarily one to one, the above

product indeed anticipates the now claimed product. The product disclosed in ,138 patent "corresponds" to the region that is now being claimed. The rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al (US Patent No. 5,965,138) and Kingham et al (Journal of General Virology, May 2001, Vol. 82, 1123-1135), for reasons of record advanced in the previous Office Action mailed 9/12/02. Applicants argue the mere fact that references can be combined or modified does not render the claims obvious unless the prior art suggest the desirability of combination or modification. In addition, applicants add that the references in either alone or in combination do not disclose or suggest the region that correspond to nucleotide positions 1 to 136,040 of GenBank accession No. AF291866, and corresponds to nucleotide positions 66 to 11,221 of GenBank accession No. L22174. Applicant's argument as part of amendment B, Paper NO. 9, filed 9/12/02 has been considered fully, but they are not persuasive. At the onset, as stated in previous action the Office made clear that ample guidance as well as motivation was provided in the above cited art to form the expression vector now being claimed. What applicants should point to is the unexpected results, if any, in view of the above ample teaching. The level of skill is high in this art and the Office maintains that in view of the teaching of the cited art no unexpected results have been presented. In addition, the applicants have not disclosed any "corresponding" regions either. Moreover, the added limitations in the newly amended claim 1 is deemed to be new, hence,

applicants assertion that the reference do not teach " correspond to nucleotide positions 1 to 136,040 of GenBank accession No. AF291866", etc..., is unsupported. The rejection is maintained.

NEW GROUNDS OF REJECTION:

Claim Rejections - 35 USC § 112

Claims 1-9, 11-14, 16, 18-21, 23-25, 28-29, 30-33, 34-36, 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "corresponds", the term "corresponds" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There are multiple long regions and multiple short regions present within the HVT and Marek's's disease virus respectively. It is not clear which regions are forming the chimeric virus. The region/ regions should be identified with appropriate sequence identification number(s). This affects the dependent claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11-14, 16, 18-21, 23-25, 28-29, 30-33, 34-36, 38-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have only disclosed the specific chimeric expression vectors identified by specific accession number, which are directed to chimeric avian herpesvirus. No other sequences or chimeric viruses which "correspond", "corresponds", or "corresponding" to the accession chimers were disclosed. The specification does not set forth the metes and bounds of "corresponding sequences", there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed regions where the region may encompass and . Therefore, a written description of the other claimed sequences or chimeras should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein

from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

No Claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

3/27/2003